

# Policy and Procedure Template: HIV/STI Post-Sexual Exposure Prophylaxis

This synopsis is intended to promote the recommended medical treatment of all patients who present for care after possible sexual exposure to HIV through sexual assault or consensual sexual activity, and to help ensure that they receive CDC recommended preventative care options for HIV, common sexually transmitted infections (STIs), and pregnancy.

A 28-day course of HIV non-occupational post-exposure prophylaxis (nPEP) should be considered for all HIV-negative persons who seek care  $\leq 72$  hours after a sexual exposure to blood, genital secretions, or other potentially infectious body fluids of a person who is living with HIV (PLWH) or is of unknown HIV status, if that exposure represents a substantial risk of HIV acquisition.

Adherence to nPEP medications is critical for nPEP effectiveness; thus, it is preferable to prescribe regimens that minimize the likelihood of side effects and reduce the number of pills that must be taken daily.

For persons seeking care after a risky sexual exposure, common sexually transmitted infections should be treated presumptively, and emergency contraception should be offered when indicated.

## Evaluation

Evaluation of the exposed patient should be conducted with the highest level of sensitivity and confidentiality. The algorithm for evaluation and treatment shown below in **Figure 1** will be used to determine the risk of HIV acquisition and the indication for nPEP.

Potential risks of nPEP outweigh benefits for persons with perceived exposures that are of negligible or no conceivable risk of HIV acquisition, and nPEP generally is not indicated under these circumstances. Clinicians should be willing to decline requests for nPEP and provide supportive counseling and referrals in these situations.

The following circumstances of the sexual exposure and decisions about nPEP management should be recorded in the medical record:

### EXPOSURE

Date and time of possible HIV exposure (did the high-risk exposure occur within the past 72 hours?).

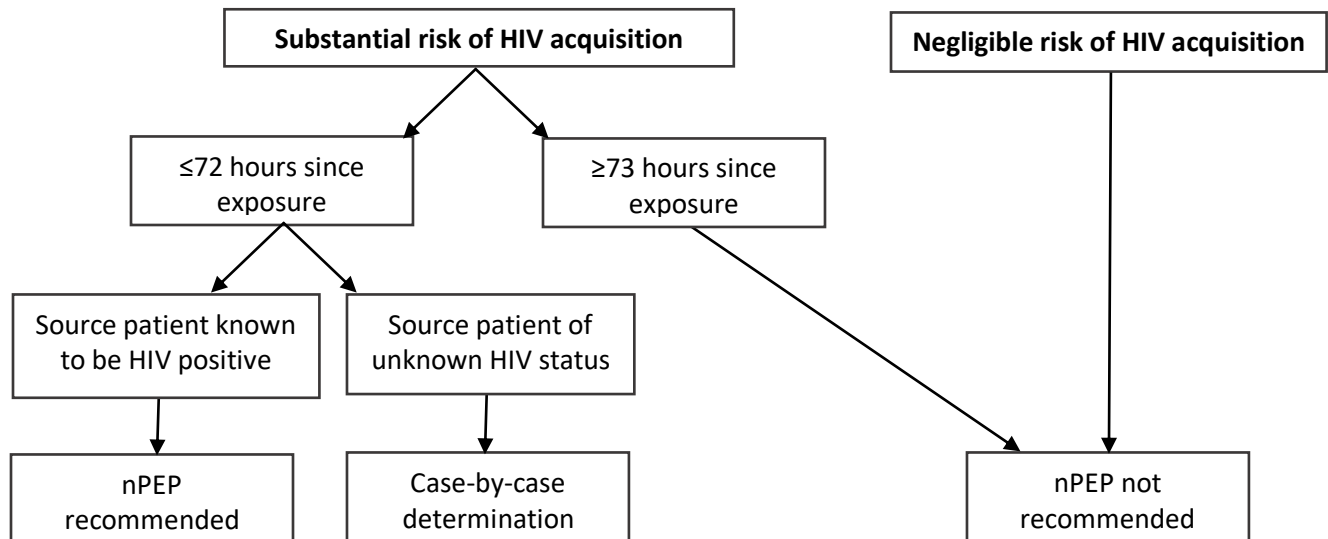
### EXPOSURE TYPE

Details of the sexual exposure, including the type of blood exposure (seminal, vaginal, blood) and route of exposure (oral, rectal, vaginal, other mucosal membrane exposure).

- The exposure should be evaluated for risk of HIV acquisition potential based on 1) the type of body fluid; 2) route of exposure; and 3) HIV status of the source patient.
- Decisions about whether to prescribe nPEP should be individualized, weighing the likelihood of HIV transmission with the potential benefits and risks of nPEP use.

- The decision to initiate nPEP is based on whether a significant exposure risk has occurred (see **Figure 1**), rather than on the age or identity of the alleged assailant.

**Figure 1. Algorithm for evaluation and treatment of possible non-occupational HIV exposure**



**Substantial risk of HIV acquisition**  
**Exposure of:** vagina, rectum, eye, mouth or other mucous membrane, nonintact skin, or percutaneous contact  
**With:** blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated with blood  
**When:** the source is known to be HIV positive

**Negligible risk of HIV acquisition**  
**Exposure of:** vagina, rectum, eye, mouth or other mucous membrane, intact or nonintact skin, or percutaneous contact  
**With:** urine, nasal secretions, saliva, sweat, or tears if not visibly contaminated with blood  
**Regardless:** of the known source or suspected HIV status of the source

*Potential risks of nPEP outweigh benefits for persons with perceived exposures that are of negligible or no conceivable risk of HIV acquisition, and nPEP is generally not indicated under these circumstances. Clinicians should be willing to decline requests for nPEP and provide supportive counseling and referrals in these situations.*

## SOURCE

Details about exposure source person(s), if available.

- HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) status.
- If the potential source person is a PLWH, try to ascertain their recent CD4 count and HIV viral load, current and previous antiretroviral therapy use, and antiretroviral resistance information.

## PATIENT

Details about the exposed patient.

- HIV, hepatitis A virus (HAV), HBV, and HCV status; vaccination history (HAV, HBV).
- Chronic medical conditions, drug allergies, and current medications and medication adherence, including pre-exposure prophylaxis (PrEP) use.
- Pregnancy status, conception plans, and breastfeeding status.
- The likelihood of pre-existing HIV infection should be determined for all individuals who present for nPEP. The following information should be obtained:
  - Has the patient ever been tested for HIV?
  - What was the result and the date of the most recent HIV test?
  - The frequency, timing, and types of HIV risk behaviors since the last negative HIV test result. The likelihood of pre-existing HIV infection should be reviewed with the patient prior to nPEP prescription.
  - If pre-existing HIV infection is suspected (e.g., the patient has symptoms of acute HIV infection such as fever or flu-like symptoms, lymphadenopathy, rash), and the HIV antigen/antibody or HIV antibody test result (see below) is negative (or "non-reactive"), a blood-based HIV nucleic acid amplification test (NAAT, or "viral load assay") should be conducted to verify the presence or absence of acute HIV infection.
- If the exposed **patient reports ongoing risk behaviors** and is HIV negative, **counsel on the option of PrEP**; transition to PrEP can occur immediately after completion of nPEP (if nPEP is not prescribed, PrEP initiation can occur once the patient is confirmed to be HIV negative and has adequate renal function).
- If a patient is already known to be HIV positive, is that person receiving HIV care? Is he or she on antiretroviral therapy and virally suppressed? If not, contact an HIV expert or infectious disease (ID) provider to link the patient to care as soon as possible.
- **HIV-positive patients do not need nPEP** (but they do need evaluation and empiric treatment for other STIs, as below).
- **With the information that is gathered, use the Evaluation and Treatment Algorithm (Figure 1) to determine the level of risk of HIV infection and the recommendation regarding nPEP.**
- If the patient is at risk of HIV infection from the reported sexual exposure (see **Figure 1**), and tests HIV negative, that patient should be offered nPEP and started on it, preferably within 1-2 hours of the exposure but as soon as possible if not, unless the patient tests HIV positive as part of the current evaluation (see Laboratory Tests, below).

## Laboratory Tests

- HIV test (preferably 4th-generation HIV Ag/Ab test) at the current visit (baseline) and again (for persons treated with nPEP) at 4-6 weeks and 3 months after nPEP initiation.
- Alanine transaminase (ALT), aspartate aminotransferase (AST), serum creatinine, and estimated glomerular filtration rate (eGFR), at baseline, 2 weeks, and 4-6 weeks follow-up if taking a tenofovir DF (TDF)-based regimen.
- HCV antibody, HBV surface antigen, HBV core antibody, and HBV surface antibody at baseline and, if negative, again at 6 months post-exposure.
- Pregnancy test for those with the potential of pregnancy.
- Syphilis serology (usually RPR or VDRL).
- If HIV seroconversion occurs during or after nPEP (HIV test is "reactive" or positive after a baseline "non-reactive" or negative test), contact an HIV expert or ID provider immediately and provide guidance to the patient as recommended by an expert. Immediate linkage to care for early antiretroviral therapy initiation and HIV primary care is essential.

- ✓ **EARLY** treatment of the exposed patient is the **PRIORITY** and should **NOT** be delayed pending receipt of laboratory test results.
- ✓ **START** nPEP if the patient has a substantial risk of infection and the HIV test result is negative.
- ✓ **INITIATE** nPEP within 1-2 hours of exposure or as soon as possible and continue for 28 days.

## nPEP Medication Regimen

If a significant exposure occurred but the patient is too distraught (e.g., following a sexual assault) to engage in a discussion about the nPEP regimen at the initial assessment, the clinician should offer a first dose of the medications and arrange for follow-up within 24 hours to further discuss the indications for nPEP.

**Preferred nPEP regimen for adolescents and adults (≥13 years of age) with normal renal function (creatinine clearance >59 mL/min):**

	Drug 1	Drug 2	Drug 3	Duration
OPTION 1	Tenofovir DF/emtricitabine (TDF/FTC) 300/200 mg (Truvada®), 1 tablet PO daily	+ dolutegravir (Tivicay®)* 50 mg, 1 tablet PO daily	-	28 days**
OPTION 2	TDF/FTC 300/200 mg (Truvada®) 1 tablet PO daily	+ raltegravir (Isentress®) 400 mg, 1 tablet PO BID	-	28 days
ALTERNATIVE	TDF/FTC 300/200 mg (Truvada®) 1 tablet once daily	+ darunavir (Prezista®) 800 mg, 1 tablet daily	+ ritonavir 100 mg, 1 tablet daily	28 days

\* *If the patient is a woman who may conceive while on the medication, or is in the early stages of pregnancy, do not prescribe dolutegravir.*

\*\* *If the pharmacist will not dispense less than a 30-day supply of nPEP medications (because of cost to the pharmacist of removing tablets from a 30-day bottle), then a prescription for a 30-day supply should be given and patients should be instructed to take medications only for 28 days.*

**Preferred nPEP regimen for adolescents and adults (≥13 years of age) with renal dysfunction (creatinine clearance ≤59 mL/min):**

	Drug 1	Drug 2	Drug 3	Duration
OPTION 1	Zidovudine and lamivudine with <i>both doses adjusted to the degree of renal function</i>	+ raltegravir (Isentress®) 400 mg, 1 tablet PO BID	-	28 days
OPTION 2	Zidovudine and lamivudine with <i>both doses adjusted to the degree of renal function</i>	+ dolutegravir (Tivicay®)* 50 mg, 1 tablet PO daily	-	28 days
ALTERNATIVE	Zidovudine and lamivudine with <i>both doses adjusted to the degree of renal function</i>	+ darunavir (Prezista®) 800 mg, 1 tablet PO daily	+ ritonavir 100 mg, 1 tablet daily (all with food)	28 days

\* If the patient is a woman who may conceive while on the medication, or is in the early stages of pregnancy, do not prescribe dolutegravir.

The dosing of TDF and FTC should be adjusted in patients with baseline creatinine clearance ≤59 mL/min. TDF should be used with caution in individuals with renal insufficiency or those who are taking nephrotoxic medications. Fixed-dose combinations should not be used in patients who need dosage adjustment.

**NOTE:** It is recommended that all individuals be tested for the presence of chronic HBV before initiating medications that are active against HBV. This would include several medications that may be used in nPEP regimens: tenofovir (TDF or TAF), emtricitabine, and lamivudine. Severe acute exacerbations of HBV (including decompensated liver disease and liver failure) have been reported in patients who discontinue HBV-active medications. Patients with HBV should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping Truvada® (TDF/emtricitabine) or other HBV-active medications. If appropriate, initiation of [chronic anti-HBV therapy](#) may be warranted.

**Pregnancy**

- For women of childbearing potential, document last menstrual period, and perform rapid urine pregnancy test. If the result is negative, and vaginal exposure to semen occurred, offer emergency contraception on site.
- Pregnancy should not preclude nPEP use, but if the patient is in the early stages of pregnancy (i.e., <8 weeks' gestation) or at risk of conceiving while on nPEP, dolutegravir should not be used.
- If the woman is <8 weeks pregnant or reports wanting to become pregnant and has normal renal function (creatinine clearance >59 mL/min), the recommended nPEP regimen is:

- TDF/FTC (Truvada®) 300/200 mg, 1 tablet PO daily + raltegravir (Isentress®) 400 mg, 1 tablet PO BID for 28 days
- Counsel on the risk of breastfeeding after a possible HIV exposure (there is a risk of transmission to the infant through breastfeeding if the mother acquires HIV).
- If alternative nPEP medication is required (e.g., renal insufficiency, pediatric patient, breastfeeding woman), consult an HIV expert or ID provider immediately, or consult with a clinician from the National Clinician Consultation Center PEpline (nccc.ucsf.edu) at 1-888-448-4911.

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**For questions, contact your HIV experts/ID providers or consult with the National Clinician Consultation Center PEP Hotline (PEpline): 1-888-448-4911**

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## Treatment for Sexually Transmitted Infections

Gonorrhea (GC), chlamydia (CT), and trichomonas (for women) should be treated presumptively if oral, vaginal, and/or anal sex occurred. Testing for GC/CT (DNA swab testing or urine testing, instead of genital swabbing) may be performed if requested by patient, but is not necessary since empiric treatment should be given, and results will not reflect the current possible exposure. Syphilis serology should be ordered with other blood tests.

- For adolescents ( $\geq 13$  years) and adults, treat for GC and CT with **ceftriaxone 250 mg IM** once, and **azithromycin 1 gram PO** once, preferably at the same time and under directly observed therapy to ensure completion of treatment.
- For women, treat empirically for trichomonas with **metronidazole 2 grams PO** once OR tinidazole 2 grams PO once; have them take it after discharge from the emergency department/clinical site if alcohol has been consumed in the previous 24 hours or if emergency contraception was taken, to minimize potential side effects and drug interactions.
- For pediatric patients ( $\leq 12$  years of age), consult [CDC guidelines](#).
- For patients 9-26 years of age who have not completed human papillomavirus (HPV) vaccinations, offer the HPV vaccine. HPV vaccination is recommended for females aged 9-26 and males aged 9-21. For men who have sex with men (MSM) who have not received HPV vaccine or who have been incompletely vaccinated, vaccine can be administered through age 26. The vaccine should be administered at the initial examination, and follow-up dose(s) administered according to the usual vaccination schedule. Assist in referring the patient for completion of the HPV vaccine series.
- Post-exposure HBV vaccination (without HBIG) should be given if the HBV serostatus of the source person is unknown and the patient has not been vaccinated previously. If the source person is known to be HBV surface antigen positive, unvaccinated exposed patients should receive both hepatitis B vaccine and HBIG. The vaccine and HBIG, if indicated, should be administered at the time of the initial evaluation, and follow-up doses of vaccine should be administered per the usual vaccination schedule.

Patients who were previously vaccinated but did not receive a post-vaccination test confirming immunity should receive a single vaccine booster dose.

**If alternative nPEP medication is required (e.g., cases involving renal insufficiency, pediatric patients), consult an HIV expert or ID provider immediately, or consult with a clinician from the National Clinician Consultation Center Hotline (PEpline)**

**888-HIV-4911 (888-448-4911)**

**9 a.m. to 8 p.m. Monday-Friday**

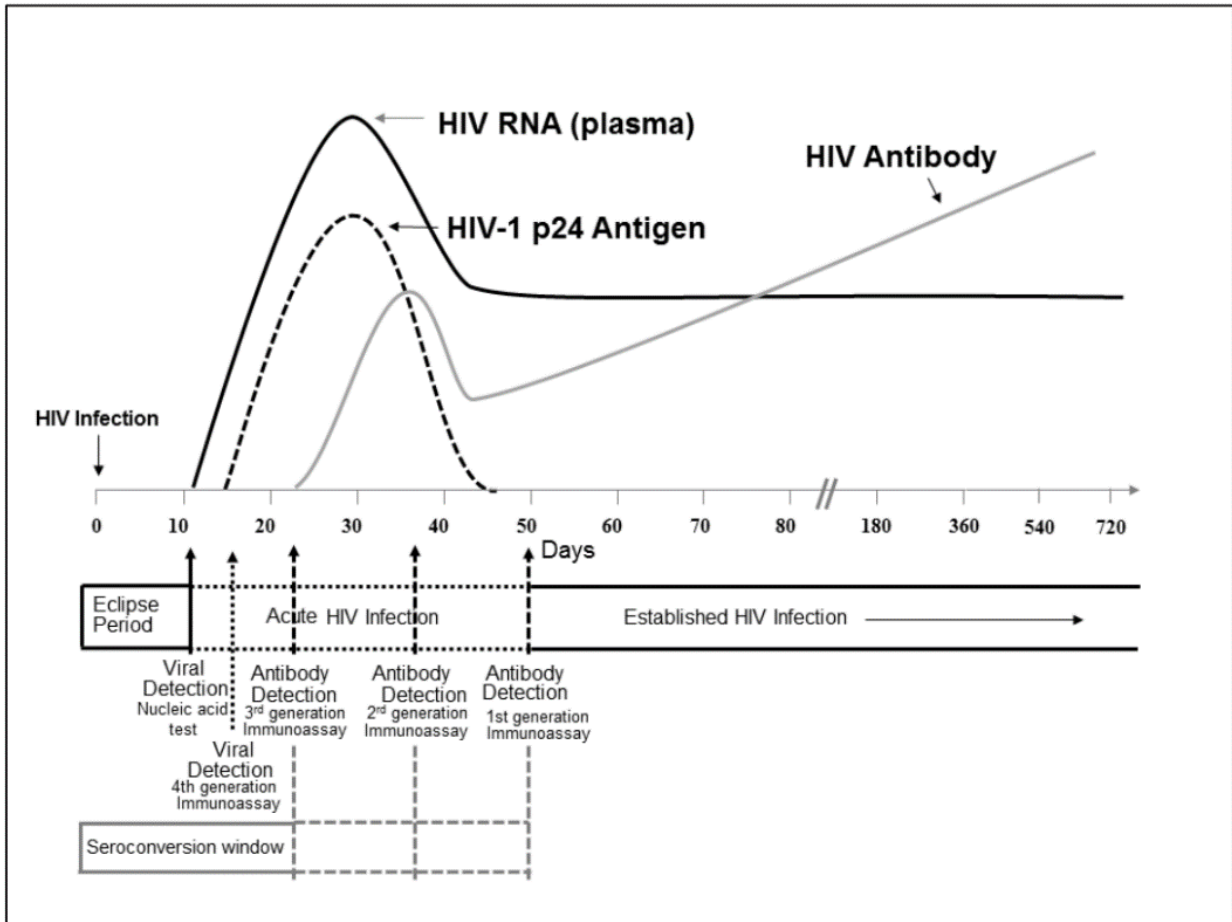
**11 a.m. to 8 p.m. on Saturday, Sunday, and holidays**

## **Patient Education**

- Instruct the patient to use condoms during vaginal and/or anal sex or abstain from sex until HIV transmission has been ruled out (with negative test results 3 months after the possible exposure) or the source person has been found to be HIV negative.
- Educate the patient on possible nPEP side effects to improve adherence (nausea, GI upset, headache, and myalgias are the most common) and consider prescribing an antiemetic to be taken before the HIV nPEP.
- Educate the patient on the importance of close adherence to the nPEP regimen.
- Reinforce the need for follow-up appointments within 24-72 hours after the initial assessment, at 4-6 weeks, and at 3 months. Assist with referring/appointment-making with the patient prior to discharge.



**Figure 2. Sequence of appearance of laboratory markers of HIV-1 infection**



*Note.* Units for vertical axis are not noted because their magnitude differs for RNA, p24 antigen, and antibody.

# LABORATORY ORDER FORM

Date: \_\_\_\_\_

Patient's Name: \_\_\_\_\_

DOB: \_\_\_\_\_

Medical Record #: \_\_\_\_\_

Diagnosis/Reason for Blood Work: \_\_\_\_\_

## Laboratory:

- HIV test (HIV Ag/Ab, if available)
- Hepatitis A total antibody
- Hepatitis C antibody
- Hepatitis B surface antigen
- Hepatitis B surface antibody
- Hepatitis B core antibody
- Pregnancy test

For those being prescribed a TDF/FTC (Truvada®)-based regimen:

- Serum creatinine for calculated eGFR
- Alanine transaminase (ALT)
- Aspartate aminotransferase (AST)

For sexual exposures, and with the patient's consent:

- Syphilis serology
- GC/CT urine NAAT
- GC/CT genital swab NAAT (if urine NAAT not available)
- GC/CT pharyngeal swab NAAT
- GC/CT rectal swab NAAT

Other \_\_\_\_\_

Other \_\_\_\_\_

## PATIENT DISCHARGE INSTRUCTIONS

You may be at risk of becoming infected with the human immunodeficiency virus (HIV) because of your sexual exposure or assault, and you have been counseled on HIV infection risk, and on medications for HIV prevention called nPEP.

- **nPEP is most effective if started as soon as possible (within 1-2 hours after the exposure or as soon as possible if longer),** but no later than **72 hours** after the exposure. nPEP should be taken for 28 days to decrease the likelihood of becoming infected with HIV.
- **It is very important to take the nPEP medicines every day, without interruption.**
- Sometimes the medicines can cause unpleasant side effects like nausea and fatigue as well as diarrhea, headaches, and rashes.
- The most common medication side effect is nausea. If you experience nausea, take the prescribed anti-nausea medicine a half hour before taking the nPEP medications.
- Some nPEP medications can interact with other prescription drugs, street drugs, or over-the-counter medications, so inform your healthcare provider if you are using any other medicines or drugs in addition to the nPEP medicines.

Call your healthcare provider if any side effects become concerning to you, because these medications SHOULD NOT be discontinued once started unless side effects are severe or life-threatening.

You will need a follow-up appointment with \_\_\_\_\_ within the next few days, at the following location \_\_\_\_\_ and phone number \_\_\_\_\_ to:

- Review your lab results and check in about any side effects that you may be having or any other any problems with taking the nPEP medications
- Determine if you should continue to take the medications

### You will be taking these medications (circled or checked):

For adults and adolescents aged  $\geq 13$  years with normal renal function (creatinine clearance  $>59$  mL/min):

- Truvada® 300/200 mg, 1 tablet once daily by mouth with dolutegravir\* (Tivicay®) 50 mg, 1 tablet by mouth once daily, with or without food, for 28 days.  
*\* Non-pregnant women **who may become pregnant** and who are not using reliable birth control and women **who are early in pregnancy** should NOT take dolutegravir.*  
**OR**
- Truvada® 300/200 mg, 1 tablet by mouth once daily with raltegravir (Isentress®) 400 mg, 1 tablet by mouth twice daily, with or without food, for 28 days.  
**OR**
- Truvada® 300/200 mg, 1 tablet by mouth once daily with darunavir (Prezista®) 800 mg, 1 tablet by mouth once daily + ritonavir (Norvir®) 100 mg, 1 tablet by mouth once daily for 28 days. This is a total of 3 pills all taken every day at the same time, with food.

For adults and adolescents aged  $\geq 13$  years with renal dysfunction (creatinine clearance  $\leq 59$  mL/min):

Zidovudine \_\_\_\_\_ + lamivudine \_\_\_\_\_ + raltegravir (Isentress<sup>®</sup>) 400 mg, 1 tablet by mouth twice daily for 28 days.

**OR**

Zidovudine \_\_\_\_\_ + lamivudine \_\_\_\_\_ + dolutegravir (Tivicay<sup>®</sup>) 50 mg, 1 tablet by mouth once daily, with or without food, for 28 days.

**OR**

Zidovudine \_\_\_\_\_ + lamivudine \_\_\_\_\_ + darunavir (Prezista<sup>®</sup>) 800 mg, 1 tablet by mouth once daily + ritonavir (Norvir<sup>®</sup>) 100 mg, 1 tablet by mouth once daily, all taken at the same time with food, for 28 days.

**FOR NAUSEA:**

Ondansetron (Zofran<sup>®</sup>) 8 mg, 1 tablet by mouth once — take one half hour before you take nPEP medications (if needed for nausea).

\_\_\_\_\_

**FOR OVERDOSE REVERSAL:**

Naloxone **spray** (2 mg/2 mL); give 1 spray in 1 nostril, then repeat after 2-3 minutes if not responding.

**IMPORTANT INSTRUCTIONS:**

- Take all nPEP medications as prescribed and at the same time every day
- Use only sterile, new needles, syringes, and equipment not used by others when injecting drugs
- Contact \_\_\_\_\_ at \_\_\_\_\_ for assistance with substance use disorder treatment
- Use a condom during sex (or abstain from sex) until we are certain you have not been infected with HIV (with negative HIV test results 3 months from today)
- Complete follow-up HIV testing and any additional testing/monitoring as instructed

Thank you for taking the difficult step to receive help.

\_\_\_\_\_  
Signature of Patient

\_\_\_\_\_  
Date/Time

\_\_\_\_\_  
Signature of Examiner

\_\_\_\_\_  
Date/Time

## REFERENCES

- U.S. Department of Health and Human Services Centers for Disease Control and Prevention. [Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States](#).
- Centers for Disease Control and Prevention and Association of Public Health Laboratories. [Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations](#). June 27, 2014.
- U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. [Sexually Transmitted Diseases Treatment Guidelines, 2015](#). Morbidity and Mortality Weekly Report. June 5, 2015. 64(3).
- U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. [Update: Interim Statement Regarding Potential Fetal Harm from Exposure to Dolutegravir – Implications for HIV Post-exposure Prophylaxis \(PEP\)](#). Attachment to Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016.
- U.S. Department of Health and Human Services. [Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States](#).

This template was created by the AIDS Education & Training Center (AETC) Program Rural Health Committee to provide a framework for healthcare facilities to use for providing medical care to patients seen for possible non-occupational blood-blood exposures to HIV. Recommendations in this template are based on the most recent guidelines of the U.S. Centers for Disease Control and Prevention at the time of its writing, August 2018. This template may be adapted for use in your healthcare facility without permission from the authors.

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